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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,080	11/21/2003	Michael Graupe	USAV2001/0082-US-CNT	2253

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EXAMINER	
ANDERSON, REBECCA L	
ART UNIT	**PAPER NUMBER**
1626	

MAIL DATE	DELIVERY MODE
04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,080	GRAUPE ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5,7,11-13,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14* is/are rejected.

7)☒ Claim(s) *1-4, 6, 8-10 and 14-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are currently pending in the instant application. Claims 5, 7, 11-13, 19 and 20 are withdrawn from consideration as being for non-elected subject matter. Claims 1-4, 6, 8-10 and 14-18 are objected. Claim 14 is rejected.

Response to Amendment and Arguments

Applicants' amendment filed 16 February 2007 has been considered and entered into the application. Applicants' amendment has overcome the objection to claims 14 and 16 for the improper Markush language. Applicants' amendment has also overcome the 35 USC 12 2nd paragraph rejection. While applicants' amendment has overcome the 35 USC 112 1st paragraph rejection of claims 1-4, 6, 8-10, 17 and 18, claim 14 has not been amended to delete the subject matter rejected and the rejection is maintained for claim 14.

In regards to the claim objection as containing non-elected subject matter, applicant argues that there is no need to limit the claims because no final rejection is present and the claims have been restricted to less than a reasonable number and the scope should be broadened. This argument is not persuasive as the restriction requirement was made under 35 USC 121. 35 USC 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the

claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. So, here we have claims, which involve more than one independent or distinct inventions. Under 35 USC 121, the claims may be restricted and the examination limited to a restricted invention. The issue here is one of restriction. 35 USC 121 gives the Commissioner the authority to restrict to one invention those applications which contain two or more inventions, i.e. limit the examination of an application to a single invention. Thus, the requirement to restrict in this application is predicated on the fact that the elected subject matter taken as a whole and the non-elected subject matter taken as a whole are so different in structure and element as to be patentably distinct, I.e. a reference which anticipated but one group of compounds would not even render obvious the other group. Accordingly, restriction as has been presented in this application is proper.

Election/Restrictions

The elected invention for search and examination is: the products of the formula (I) in which:

X1 is –NHC(R1)(R2)X3;

R1 is hydrogen or (C1-6)alkyl;

R2 is selected from the group consisting of hydrogen, -R12, -R14,

R12 is hydrogen, (C1-5)alkyl or halo-substitued (C1-6)alkyl

R14 is (C3-10)cycloalkyl(C0-6)alkyl, (C6-10)aryl(C0-6)alkyl or (C9-10)bicycloaryl(C0-6)alkyl;

X3 is benzooxazol-2-ylcarbonyl;

X7 is hydrogen;

R3 is C(R6)(R6)X6;

R6 is hydrogen or (C1-6)alkyl

X6 is X5S(O)2R14

X5 is a bond or (C1-6)alkylene; and

X2 is morpholin-4-ylcarbonyloxy.

The requirement is still deemed proper and is FINAL.

Claim Objections

Claims 1-4, 6, 8-10 and 14-18 are objected to as containing non-elected subject matter. Claims 1-4, 6, 8-10 and 14-18 presented drawn solely to the elected invention as identified supra as **the elected invention for search and examination** would overcome this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound of the formulas (I), its stereoisomer, prodrug and pharmaceutically acceptable salt and solvate thereof does not reasonably provide enablement for the N-oxide derivative, any prodrug derivative, protected derivative, individual isomer or mixture of isomers. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention is the compounds of the formula I and its N-oxide derivatives, prodrug derivatives, protected derivatives, individual isomers and mixtures of isomers, and pharmaceutically acceptable salts and solvates thereof.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that an isomer is any compound having the same composition, including constitutional isomers, which are compounds whose atoms are connected differently and stereoisomers. Constitutional isomers can contain different functional groups in varying positions. The term "derivative" found in the claims is defined as a compound, usually organic obtained from another compound by a simple chemical process or an organic compound containing a structural radical similar to that from which it is derived (Hackh's chemical dictionary, 1972). Therefore, the term "derivative" found in the claims renders the claims indefinite because it is unclear what

compounds are being claimed, i.e. what similar radical is found in the derivative of hydroxamic acid of the formula (I) and encompassed by the instant claims

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is for the compound of the formula I, its stereoisomers, prodrugs and pharmaceutically acceptable salts or solvates of the compound. There is no data present in the instant specification for an alternate definition to the term derivative, nor the preparation of constitutional isomers, or protected derivatives or N-oxide derivatives of the instant compound of the formula I.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include any isomer, i.e. any compound with the same number of each atom or any compound containing a structural radical similar to that from the compounds of the formula (I)

The quantity or experimentation needed and the level of skill in the art

While the level of the skill in the pharmaceutical arts is high, it would require undue experimentation of one of ordinary skill in the art to prepare any isomer or derivative of the formula I as instantly claimed since an isomer of the compounds of the formula I need only have the same composition of atoms, not necessarily the same order of atoms and can have varying functional groups in varying positions. The only guidance present in the instant specification is for the compound of the formula I and its

stereoisomer, prodrug and pharmaceutically acceptable salt and solvate thereof. There is no guidance or working examples present for constitutional isomers or derivatives of the formula I. Therefore, the claims lack enablement and this rejection can be overcome, for example, by deleting the phrase "and the N-oxide derivatives, prodrug derivatives, protected derivatives, individual isomers and mixtures of isomers;" from the instant claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

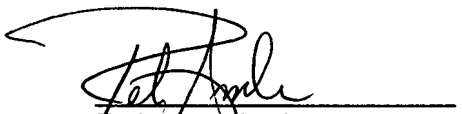
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



26 April 2007

Rebecca Anderson
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Art Unit 1626, Group 1620
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